

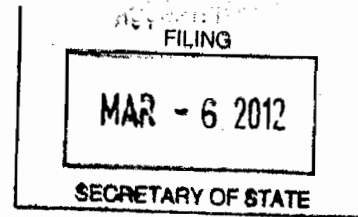
Rule-Making Cover Sheet

MAPA-1

TO: **Secretary of State**
ATTN: **Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333.**

2012-65

1. **Agency:** Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy
2. **Agency umbrella and unit number:** 02-392
(2 digit umbrella # and 3 digit unit #) *RETAIL*
3. **Title of rule:** Operation of ~~Wholesale~~ Drug Outlets
4. **Chapter number assigned to the rule:** 13
(must be 3 digits or less)
5. **Date(s)/method(s) of notice:** Newspaper advertisement by Secretary of State, 10-12-11; mailing to interested parties, 09-29-11; posting on OPOR's web site, 09-28-11
6. **Date(s)/place(s) of hearing(s):** 11-03-11, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME
- 7-A. **Type:** ☐ new rule ☒ partial amendment(s) of existing rule
☐ suspension of existing rule ☐ repeal of rule ☐ emergency rule
☐ repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.
8. **Name/phone of agency contact person:** Geraldine Betts, Board Administrator, (207) 624-8625
9. **If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following**
☐ Provisional adoption (prior to Legislative review) ☐ Final adoption
☐ Emergency adoption of major-substantive rule



10. **Certification Statement:** I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on February 2, 2012.

Signature: _____

(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

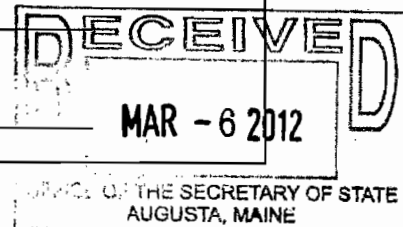
11. **Approved as to form and legality by the Attorney General on** 3/1/12

(date)

Signature: _____

(original signature, personally signed by an Assistant Attorney General)

Printed Name: Christopher L. MANK



EFFECTIVE DATE: MAR 11 2012

Part 3 - Operation of Drug Outlets

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 13: OPERATION OF RETAIL DRUG OUTLETS

Summary: This chapter sets forth operation requirements for retail drug outlets registered by the board.

1. Cleanliness and Sanitation

The pharmacy department shall at all times be operated in a clean and sanitary manner.

2. Hours of Operation; Posting of Hours

1. Minimum Hours of Operation

A retail drug outlet must be open to the public for a minimum of 40 hours per week unless waived by the board for good cause shown, and must be staffed by a pharmacist at all times that the drug outlet is open.

2. Posting of Schedule

A retail drug outlet shall prominently post in a public area of the store the days and hours that the drug outlet is scheduled to be open to the public.

3. Adherence to Posted Schedule

A retail drug outlet shall adhere to the schedule posted pursuant to Section 2(2) of this chapter.

4. Deviations From Posted Schedule

A retail drug outlet shall prominently post in a public area of the store any deviation from its posted schedule as soon as the need to deviate from the posted schedule is known by the drug outlet. This posting shall include the period of time the drug outlet will be closed and the name, street address and telephone number of a nearby drug outlet that is available to serve the public during the period of closure.

5. Reporting of Deviations to Board

Except as set forth in this subsection, a retail drug outlet shall report any deviation from its posted schedule to the board by fax or email no later than the next business day following the deviation. Each day on which a deviation occurs must be separately reported. Reporting may be made by mail if the drug outlet does not have fax or email capability.

No report need be filed for:

- A. A deviation of less than four hours duration;
- B. A deviation resulting from severe weather conditions, fire, flood, disaster or natural or man-made catastrophe beyond the control of the drug outlet.

6. Remedial Action by Board

In the event that a retail drug outlet deviates four or more times from its posted schedule within a calendar month, other than for reasons described in Section 2(5) of this chapter, the board, following notice and opportunity for hearing, may require the drug outlet to revise the schedule posted pursuant to Section 2(2) of this chapter as may be necessary to protect the public from injury or inconvenience due to the drug outlet's inability to adhere to its posted schedule.

3. Pharmacist in Charge

1. Generally

The business of a retail drug outlet shall be conducted under the direct supervision of a licensed pharmacist who has registered as the pharmacist in charge of that drug outlet with the board. No retail drug outlet may operate without a pharmacist in charge.

2. Responsibilities

The pharmacist in charge is responsible legally and professionally for all activities related to the practice of pharmacy within the retail drug outlet for which the licensee is registered as pharmacist in charge, and for the drug outlet's compliance with the provisions of the Maine Pharmacy Act, the rules of the board, and the federal laws and rules specified in Chapter 29, Section 1 of the board's rules. The responsibilities of the pharmacist in charge include, but are not limited to:

- A. The drug outlet's procedures for the procurement, storage, compounding and dispensing of drugs;

- B. The recordkeeping systems required in the practice of pharmacy for the purchase, sale, possession, storage and repackaging of drugs;
- C. The security of the prescription filling area and its contents;
- D. Ensuring that the prescription filling area is operated in conformance with good pharmaceutical practices;
- E. Notifying the board of termination of status as pharmacist in charge via letter, fax or email within 7 days of the termination; and
- F. The supervision of pharmacy technicians and performance of administrative responsibilities relating to pharmacy technicians as required by Chapter 7 of the board's rules.

3. Presence at Retail Drug Outlet

Except as set forth in Section 3(4) of this chapter, or unless waived by the board for good cause shown, a pharmacist in charge of a retail drug outlet shall practice at that drug outlet for a minimum of 30 hours per week or 50% of the hours the drug outlet is open, whichever is less.

4. Registration as Pharmacist in Charge for More Than One Retail Drug Outlet

Except as set forth in Section 3(5)(B) of this chapter, no pharmacist may register or serve as pharmacist in charge for more than one retail drug outlet prior to receiving approval from the board. All requests for approval, including requests for emergency approval made pursuant to Section 3(5) of this chapter, must be made via letter, email or fax. The board may grant approval only in the following circumstances upon a consideration of the nature and extent of the risk posed to the public:

- A. Death, incapacity, emergency medical leave or unexpected resignation or discharge of a pharmacist in charge;
- B. Specialty practice setting which does not require a 30 hour/50% pharmacist in charge for reasonable protection of the population served (e.g., opiate treatment program); or
- C. Other situations where exigent circumstances warrant the registration of a sole pharmacist in charge of more than one retail drug outlet.

The board's order of approval may be of fixed or of indeterminate duration and shall contain such coverage requirements and other provisions as may be necessary to protect the public health and safety at all locations to be served by a sole pharmacist in charge.

5. Emergency Requests

A request for approval pursuant to Section 3(4)(A) of this chapter must be made within 7 days after the death, incapacity, commencement of emergency medical leave or unexpected resignation or discharge of a pharmacist in charge. Providing that the request was made within this time period,

- A. The board administrator or the administrator's designee may rule on the request on an interim basis until the board is able to address it; and
- B. The retail drug outlet may operate under the supervision of a pharmacist pending the interim ruling of the board administrator or the administrator's designee.

4. Death, Incapacity or Sudden Unavailability of Pharmacist on Duty

A retail drug outlet shall immediately cease filling and dispensing prescription drug orders upon the death, incapacity or sudden unavailability of a sole pharmacist on duty until a replacement pharmacist arrives at the drug outlet.

5. Prescriptions to be Filled Only in Prescription Filling Area

Prescriptions may only be filled and dispensed in the prescription filling area of the retail drug outlet. A retail drug outlet may request a waiver of this limitation from the board by demonstrating, to the satisfaction of the board, that a lack of convenient public access to a retail drug outlet exists and that the public health and safety requires that drugs be dispensed at a location remote from the retail drug outlet.

Nothing in this section shall prevent a retail drug outlet from delivering a prescription to the home or business of a patient under arrangements supervised by a pharmacist.

6. Security of Prescription Filling Area

1. Absence of Pharmacist From Prescription Filling Area

A retail drug outlet and pharmacist on duty shall ensure that no person remains in the prescription filling area during the absence of a pharmacist from the prescription filling area other than an authorized pharmacy technician or an authorized person.

2. Dispensing of Prescriptions in the Absence of a Pharmacist

No retail drug outlet may dispense prescription drugs pursuant to an original prescription drug order in the absence of a pharmacist from the prescription filling area. No retail drug outlet may dispense prescription drugs pursuant to a renewal prescription drug order in the absence of a pharmacist from the store premises.

3. Acceptance of Walk-In Prescription Drug Orders in the Absence of a Pharmacist

An authorized pharmacy technician may accept prescription drug orders from walk-in patients in the absence of a pharmacist from the prescription filling area only when the pharmacist-

- A. Is taking a customary and reasonable work break;
- B. Is in the vicinity of the store in which the retail drug outlet is located;
- C. Is not engaged in any activity that would interfere with his/her immediate availability; and
- D. Is reachable by the authorized pharmacy technician during the absence.

4. Deployment of Barrier

During the absence of a pharmacist or authorized pharmacy technician from the prescription filling area, the prescription filling area shall be secured with a barrier that extends from the floor or counter to the ceiling. The barrier must be constructed of a material of sufficient strength so that the barrier cannot be readily removed, penetrated or bent. If the barrier is constructed of non-solid material, any openings or interstices must be small enough to prevent the removal, by any means, of items from the prescription filling area. If, in addition, there is no authorized person in the prescription filling area, the barrier shall also be locked. The retail drug outlet and pharmacist in charge shall ensure that only a pharmacist or authorized person possesses or has access to the key, combination or activation code to the lock.

5. Alarm

The prescription filling area shall be protected by an electronic security system. The electronic security system must be separate from any other electronic security system that may be installed at the retail drug outlet, and must be capable of activation/deactivation separately from any other electronic security system that may be installed at the retail drug outlet. The drug outlet shall activate the electronic security system during the absence of a pharmacist, pharmacy technician or authorized person from the prescription filling area. The retail drug outlet and pharmacist in charge shall ensure that only a pharmacist or authorized person possesses or has access to the key, combination or activation code to the electronic security system.

6. Security Cameras

A retail drug outlet shall deploy security cameras sufficient in number to monitor the critical areas of the pharmacy department, including, at a minimum, the prescription filling area, self-service customer kiosks, dispensing machines that are part of an automated pharmacy system, the narcotics safe and the checkout area. The cameras shall operate continuously, without interruption, 24 hours per day each day of the year. The cameras shall continuously record and store images of the monitored area at a frequency of no less than 15 frames per second. A retail drug outlet shall retain stored images for no less than 30 days after recordation and shall produce the stored images to the board upon request.

7. Implementation of Barrier, Alarm and Security Camera Requirements

A retail drug outlet that is not in compliance with the barrier, alarm and security camera requirements of Section 6, subsections 4, 5 and 6 shall bring itself into full compliance upon any alteration of the prescription filling area that requires approval of the board pursuant to Chapter 8, Section 7 or by June 30, 2010, whichever first occurs.

8. Designation of Authorized Persons and Authorized Pharmacy Technicians

A pharmacist in charge shall report on a form supplied by the board the name and other identifying information of all authorized persons and authorized pharmacy technicians designated by the pharmacist in charge.

9. Deliveries and Delivery Logs

- A. All shipments containing only prescription drugs shall be delivered in unopened containers to a pharmacist, authorized pharmacy technician or authorized person. Only a pharmacist, authorized pharmacy technician or authorized person may sign for the delivery.
- B. A retail drug outlet shall maintain a log of all prescription drugs delivered to rural health centers and free clinics; and to dispensaries, hospital pharmacies, extended care facilities, boarding homes, nursing homes, drug abuse treatment centers, penal institutions, family planning centers, medical clinics and all other facilities that are not registered or licensed by the board. The log shall show the date and time of delivery, the name of the person making delivery on behalf of the retail drug outlet, the drugs delivered, the name and address of the institution receiving the drugs, and the name of the person accepting delivery on behalf of the institution.
- C. A rural health center or free clinic; or a dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center, penal institution, family planning center, medical clinic or any other facility that is not registered or licensed by the board; shall maintain a log of all prescription drugs delivered to it by a retail drug outlet. The log shall show the date and time of delivery, the name of the retail drug outlet making delivery, the name of the person making delivery on behalf of the retail drug

outlet, the drugs received, and the name of the person accepting delivery on behalf of the institution.

7. Signs

All retail drug outlets shall identify their location by an interior or exterior sign that identifies the establishment as a drug outlet through the word or words "pharmacy," "druggist," "drugs," "drug store," "Rx," "apothecary," or the like. The drug outlet may display the sign upon issuance of the drug outlet's certificate of registration by the board. The sign must be immediately removed or covered upon the nonrenewal, surrender or revocation of the establishment's registration as a drug outlet, or upon the permanent closing of the drug outlet.

8. Permanent Closing of a Retail Drug Outlet

1. Notification

- A. A retail drug outlet shall notify the board of the drug outlet's permanent closing at least 14 days prior to closing. The notice shall include the name and address of the drug outlet to be closed; the date of closure; the name and address of the drug outlet acquiring the prescription inventory; and the name and address of the drug outlet acquiring the prescription files and patient profiles.
- B. A retail drug outlet shall notify the DEA of the drug outlet's permanent closing at least 14 days prior to closing. The notice shall include the name, address, and DEA registration number of the drug outlet to be closed; the name, address, and DEA registration number of the drug outlet acquiring the controlled substances; and the date on which the transfer will occur.
- C. A retail drug outlet shall notify the general public of the drug outlet's permanent closing at least 14 days prior to closing. The notice shall include the date of closure and the new location of the drug outlet's patient prescription files. Notice shall be given by prominent posting in a public area of the store and by display advertisement in a newspaper of general circulation in the area served by the drug outlet.

2. Closing day procedures

- A. The retail drug outlet shall take a complete inventory of all controlled substances.
- B. The retail drug outlet shall dispose of controlled substances as follows:
 - (1) If the controlled substances are being sold or given to another DEA registrant-

- (a) The transfer of Schedule II controlled substances shall be made on closing day and memorialized by a properly executed DEA Form 222; and
 - (b) The transfer of Schedule III, IV, and V controlled substances shall be made on closing day and memorialized by invoice, with copies to each party and the board.
 - (2) If the controlled substances are not being sold or given to another DEA registrant, the retail drug outlet shall turn over to the board on closing day for safekeeping, at the sole expense of the drug outlet, all controlled substances in its possession, custody or control, together with appropriate inventory information. The drug outlet shall lawfully sell or dispose of these drugs within 60 days after closure. If the drug outlet fails to lawfully sell or dispose of these drugs within that time, the drugs shall be deemed forfeit to the board on the 61st day after closure without need of any action by the board. The board shall then dispose of the drugs with no compensation to the drug outlet. In the event of forfeiture as set forth herein, the retail drug outlet remains liable for all costs incurred by the board in the transportation, safekeeping and disposition of the drugs.
- C. The retail drug outlet shall dispose of prescription legend drugs as follows:
- (1) If the prescription legend drugs are being sold or given to another drug outlet, the bulk transfer of such drugs shall be made on closing day and memorialized by invoice, with copies to each party.
 - (2) If the prescription legend drugs are not being sold or given to another drug outlet, the retail drug outlet shall turn over to the board on closing day for safekeeping, at the sole expense of the drug outlet, all prescription legend drugs in its possession, custody or control, together with appropriate inventory information. The drug outlet shall lawfully sell or dispose of these drugs within 60 days after closure. If the drug outlet fails to lawfully sell or dispose of these drugs within that time, the drugs shall be deemed forfeit to the board on the 61st day after closure without need of any action by the board. The board shall then dispose of the drugs with no compensation to the drug outlet. In the event of forfeiture as set forth herein, the retail drug outlet remains liable for all costs incurred by the board in the transportation, safekeeping and disposition of the drugs.
- D. Disposition of prescription files and patient profiles
- (1) If the prescription files and patient profiles are being sold to another drug outlet or are being transferred to another drug outlet in the same chain, the retail drug outlet that is closing shall transfer the files and profiles on closing day. The recipient drug outlet must keep the files and profiles for the time required by Chapter 24 of the board's rules.

- (2) If the prescription files and patient profiles are not being sold or transferred, the retail drug outlet shall find a drug outlet within a reasonable distance that is willing to be custodian of the records. The custodian drug outlet must keep the files and profiles for the time required by Chapter 24 of the board's rules.

E. Security. The retail drug outlet shall ensure the security of its drug supply at all times during the closing procedures.

3. Reports and Returns Due After Closing

Within 30 days after closing, the retail drug outlet shall make the following reports and returns:

A. To DEA-

- (1) Name, address, and DEA number of the closed drug outlet;
- (2) Return of any unused DEA Form 222s;
- (3) Copy of the controlled substances inventory and all schedules; and
- (4) Copies of DEA Form 222 completed pursuant to Section 8(2)(B)(1)(a) of this chapter.

B. To the board-

- (1) Return of the license for the closed retail drug outlet;
- (2) Report that all signs indicating the presence of the closed drug outlet have been removed;
- (3) Report that all labels and blank prescriptions have been destroyed;
- (4) Report that the DEA license and all unused DEA Form 222s have been returned to the DEA;
- (5) Report as to the disposition of controlled substances and prescription legend drugs made pursuant to Section 8(2)(B) and (C) of this chapter; and
- (6) Report as to the disposition of prescription files and patient profiles made pursuant to Section 8(2)(D) of this chapter.

4. Chemicals and Hazardous Materials

The retail drug outlet shall remove and dispose of all chemicals and hazardous materials prior to closing in accordance with the Hazardous Waste Management Rules of the Department of Environmental Protection identified in Chapter 23, Section 2(1) of the board's rules (as applicable). The drug outlet is responsible for all costs directly and indirectly incurred by the board in removing and disposing of chemicals and hazardous materials that the licensee fails to remove from the premises.

STATUTORY AUTHORITY: 32 M.R.S.A. §§13720, 13721(1), 13722, 13723, 13751

EFFECTIVE DATE:

November 8, 2004 - filing 2004-515